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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,129	04/11/2005	Satoshi Saito	03419.0023-00	8898

22852 7590 05/07/2010

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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
05/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,129	SAITO ET AL.	
	Examiner	Art Unit	
	SCOTT LONG	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 16-18* is/are rejected.

7)☒ Claim(s) *4 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/23/2010 has been entered.

Claim Status

Claims 1-7 and 16-18 are pending. Claim 8-15 and 19 are cancelled. Claims 1 and 16-18 are amended.

Priority

This application claims benefit as a 371 of PCT/JP03/02833 0 (filed 3/11/2003). This application also claims benefit from the foreign application JAPAN 2002-065880 (filed 03/11/2002). Therefore, the instant application has been granted the benefit date, 3/11/2002, from the foreign application JAPAN 2002-065880.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 23 March 2010 consisting of 1 sheet is in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

37 CFR 1.132 Declaration

The examiner acknowledges receipt of the Declaration under 37 CFR 1.132 by Dr. Toru Onishi filed on 23 March 2010.

The Declaration under 37 CFR 1.132 filed 23 March 2010 is insufficient to overcome the rejection of claims 1-7 and 16-18 based upon *obviousness over Porro et al. (WO99/14335)* as set forth in the last Office action because:

The affiant has provided a table and comments comparing lactic acid production and lactic acid yield among systems present in several references, including the instant application and Porro et al.

The examples chosen by the applicant from Porro et al. (Tables A and 3A) describe lactic acid production and lactic acid produced by a *S. cerevisiae* has been transformed with a plasmid comprising a polynucleotide encoding LDH operatively linked to a TPI promoter. The affiant has compared this particular example from Porro to the claimed system which recited that the LDH is integrated into the genome of the claimed microorganism. While the lactic acid yield from the Porro system and the lactic acid yield produced by the instantly claimed system are nearly identical, the affiant,

states in item 15: "the claimed transformants…containing a single copy of LDH gene incorporated into the chromosome, produced lactic acid in the amount larger than, or at least similar to, the amount of lactic acid produced from the yeast transformants carrying multiple copies of LDH gene, as disclosed in …Porro. In summary, the claimed transformants showed an increased efficiency of lactic acid production from introducing only a single copy of an LDH gene compared to the yeast cells introducing multiple copies of an LDH gene" (Decl. page 5 bridging page 6). The affiant further states in item 17: "Porro, provide[s] no reason to expect an increased efficiency of lactic acid production from the chromosomally-integrated LDH gene."

The examiner does not find these statements sufficient to overcome the pending rejection because:

(1) Table 1 of the Declaration shows the present application produces 32.8% lactic acid yield, while Porro (WO99/14335) produces 33.8% lactic acid yield; the yields of these systems are nearly identical. On its surface, this comparison does not seem to suggest any unexpected characteristic of the claimed invention.

(2) The applicant emphasizes "an increased efficiency of lactic acid production from the chomosomally-integrated LDH gene." Fermentation Efficiency is a different measure from Fermentation Yield. Fermentation efficiency is an expression of how much lactic acid was actually produced relative to the amount that could be theoretically produced, while Fermentation yield is a percentage measure of the mass of lactic acid produced per mass of glucose consumed. The specification and affidavit do not specify the theoretical amount of lactic acid that is predicted to be produced by a given amount

of glucose in a transformant having a chomosomally-integrated LDH gene.

(3) The fermentation efficiency and fermentation yield are partially determined by the strain of *S. cerevisiae* used and medium used in a particular fermentation process. The examiner draws the affiant's attention to Table 1, columns 5 & 6 (Decl. page 4). According to these columns, the genetic structure of the *S. cerevisiae* is identical, having a bovine LDH gene integrated into the genome of the yeast. However, the lactic acid yield in column 5 (post-filing art by instant inventors, Ishida et al.) is nearly double that disclosed in column 6 (the instant application). The media used is similar, YPD10 (for Ishida et al.) and YPD (for instant application). The examiner looked at the Tables and Figures for these columns, disclosed by affiant as the source of data found in the columns, and discovered that Ishida et al. used the particular yeast strain, *S. cerevisiae* YIBO-7A, while the instant application used the particular yeast strain *S. cerevisiae* KCB-27. It is well known in the art that even various strains of *S. cerevisiae* can result in different yields of fermentation products. Therefore, as both columns 5 and 6 disclose a transformed *S. cerevisiae* having a bovine LDH gene integrated into its genome, and yet produce significantly different yields of lactic acid, the examiner suggests that the asserted "unexpected" high yield of the claimed invention may not be solely due to a chromosomally-integrated LDH gene.

In addition to the facts provided above, the examiner notes that the Affiant is the same as the Inventor of the instant application. Therefore, the Affiant has an interest in the outcome of the instant application.

In assessing the weight to be given expert testimony, the examiner may properly

consider, among other things, the nature of the fact sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion. See Ex parte Simpson, 61 USPQ2d 1009 (BPAI 2001), Cf. Redac Int'l. Ltd. v. Lotus Development Corp., 81 F.3d 1576, 38 USPQ2d 1665 (Fed. Cir. 1996), Paragon Podiatry Lab., Inc. v. KLM Lab., Inc., 948 F.2d 1182, 25 USPQ2d 1561, (Fed. Cir. 1993).

Affidavits or declarations are provided as evidence and must set forth facts, not merely conclusions. In re Pike and Morris, 84 USPQ 235 (CCPA 1949).

Upon consideration of the facts taught by the cited art and the information submitted by the Affiant, the balance of evidence indicates that the prior art teaches the instantly claimed inventions.

RESPONSE TO ARGUMENTS

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 6-7 and 16-18 remain rejected under 35 U.S.C. 103(a) as being obvious over Porro et al. (WO99/14335) for the reasons of record and the comments below. The rejection of claims 4-5 under 35 U.S.C. 103(a) as being obvious over Porro et al. (WO99/14335) is withdrawn due to the applicant's arguments.

The applicant's arguments have been fully considered and are partially persuasive.

The applicant has amended the instant claims to clarify the instant claims.

Furthermore, the applicant has submitted a 37 CFR 1.132 Affidavit by Dr. Toru Onishi which was found insufficient to overcome the pending rejection.

The applicant argues “the inventors presented the unexpected results related to the claimed transformants” and particularly indicate the transformants of *S. cerevisiae* strain IF02260, identified as KCB-27, KCB-210, and KCB-211 possess such unexpected properties (Remarks, page 9, lines 7-10). The applicant further indicates that “increased efficiency" of L-lactic acid production by the claimed transformants compared to the prior art is the inventive feature of the claimed invention. As mentioned in earlier actions, “increased efficiency” is not defined in the specification. It is a vague term. In the field of Fermentation, “fermentation efficiency” can be viewed as an expression of how much product (e.g., lactic acid) was actually produced relative to the amount that could be theoretically produced. The specification does not predict a theoretical amount of lactic acid that can be produced by the claimed transformants. Therefore, the examiner has chosen to consider advantages such as not losing the plasmid curing culturing as an “efficiency." Essentially, the claims do not reflect any

unexpected feature of "efficiency." Repeating the word, "efficiency," throughout this or future arguments will not overcome the pending rejection.

The applicant further suggests (Remarks, page 10) that skilled artisans, being aware of Porro (WO99/14335) would have pursued a plasmid embodiment, rather than an embodiment where LDH is integrated into the genome of a transformant. The examiner finds this argument unpersuasive, since Porro teaches (at pages 64-66) claims 1, 16, 19-21, which together claim a specific embodiment, a recombinant yeast strain comprising a bovine LDH gene operatively linked to a pyruvate decarboxylase promoter, wherein the gene coding for lactate dehydrogenase is integrated in the yeast genome. This is almost the same as the claimed transformant. Therefore, a skilled artisan understanding that Porro not only envisioned, but explicitly claimed an embodiment of transformed yeast having a chromosomally-integrated LDH gene, would be motivated to practice his invention. Therefore, the applicant's arguments are unpersuasive.

The applicant argues that limitations of claims 4 and 5 are not explicitly taught by Porro et al. (WO99/14335) and therefore should not be rejected in the pending rejection. Claims 4-5 recite SEQ ID NOs: 3-4. SEQ ID NO:3 is a homologue of bovine lactate dehydrogenase which has been codon optimized for expression in Saccharomyces cerevisiae. SEQ ID NO:4 is the DNA sequence which encodes a homologue of bovine lactase dehydrogenase which has been codon optimized for expression in Saccharomyces cerevisiae. Porro et al. explicitly claims a transformed yeast comprising a bovine lactate dehydrogenase gene (page 65, claim 17). The rejection

(from Action, filed 11/23/2009) states, "Furthermore, codon optimization of the bovine lactate dehydrogenase gene for expression in Saccharomyces cerevisiae is well known in the art and therefore obvious." However, as a sequence search has been performed for SEQ ID NO:3 and SEQ ID NO:4 and no prior art has been discovered, these particular codon optimizations of the bovine lactase dehydrogenase sequence is non-obvious. Accordingly, the examiner withdraws the rejection of claims 4-5.

Accordingly, the examiner hereby maintains the rejection of claims 1-3, 6-7 and 16-18 under 35 U.S.C. 103(a) as being obvious over Porro et al.

The examiner reiterates the pending rejection:

Claims 1-3, 6-7 and 16-18 are rejected under 35 U.S.C. 103(a) as being obvious over Porro et al. (WO99/14335).

Claim 1 is directed to a bacterial or yeast transformant into which has been incorporated a lactate dehydrogenase gene, there the lactate dehydrogenase gene encodes for a foreign protein having lactate dehydrogenase activity and provided with pyruvic acid substrate affinity that equals or exceeds the pyruvic acid substrate affinity of the pyruvate decarboxylase inherent in the host organism, wherein a single copy of the lactate dehydrogenase gene has been incorporated such that it is under the control of a genomic pyruvate decarboxylase gene promoter on the host chromosome, or such that it is under the control of a structural and functional homologue of the genomic pyruvate decarboxylase gene promoter, which replaces the genomic pyruvate decarboxulase gene promoter on the host chromosome, and wherein the pyruvate decarboxylase gene on the host chromosome is replaced with the single copy of the

lactate dehydrogenase gene. Porro et al. teach, "yeast strains…transformed with at least one copy of a gene coding for lactic dehydrogenase (LDH) functionally linked to promoter sequences allowing the expression of said gene in yeasts" (page 4, lines 6-11). Porro et al. teach, "yeast strains having…a reduced pyruvate decarboxylase activity and transformed with…a gene coding for lactic dehydrogenase (LDH) functionally linked to promoter sequences" (page 4, lines 12-17). Porro et al. teach any yeast promoter…may be used according to the invention…the promoter of pyruvate decarboxylase gene of K. lactis (KlPDC) is particularly preferred (page 14, lines 18-28). Porro et al. further teach, "Pyruvate decarboxylase gene promoters…are particularly preferred" (page 15, lines 2-5). Porro et al. describe making a triple deletion of the pyruvate decarboxylase genes encoding PDC1, PDC5, and PDC6, using homologous recombination (page 8, lines 25-27). Porro et al. further teach that "PDC genes are highly conserved among different yeast genera" (page 9, lines 7-9). Porro et al. also teach "integrative vectors can be obtained by using homologous DNA sequences in certain regions of the host genome, allowing, by homologous recombination, integration of the vector" (page 12, lines 12-15).

Claim 2 is directed to the transformant according to claim 1, wherein the foreign protein is a bovine-derived lactate dehydrogenase or its homologue. Porro et al. teach, "the gene coding for lactate dehydrogenase may be of any species (e.g. mammalian, such as bovine)" (page 9, lines 29-30).

Claim 3 is directed to the transformant according to claim 1, wherein the foreign protein is a protein comprised of the amino acid sequence shown in sequence number 1

or its homologue. SEQ ID NO:1 is the bovine lactate dehydrogenase gene. Clearly, Porro et al. contemplates the amino acid encoded this gene or its homologue. Porro et al. teach, "the gene coding for lactate dehydrogenase may be of any species (e.g. mammalian, such as bovine)" (page 9, lines 29-30). Furthermore, Porro et al. explicitly claims a transformed yeast comprising a bovine lactate dehydrogenase gene (page 65, claim 17).

Claim 6 is directed to the transformant according to any of claims 1 through 5, wherein the host organism belongs to the Saccharomyces family.

Claim 7 is directed to the transformant according to any of claim 1, wherein the host organism is Saccharomyces cerevisiae. Porro et al. teach transformed yeast, Saccharomyces cerevisiae.

Claim 16 is directed to a transformant of the Saccharomyces family into which a single copy of a lactate dehydrogenase gene, wherein the lactate dehydrogenase gene encodes a bovine-derived lactate dehydrogenase or its homologue and has been incorporated such that the lactate dehydrogenase gene is under the control of a genomic pyruvate decarboxylase 1 gene promoter on the host chromosome of the Saccharomyces family or such that the lactate dehydrogenase gene is under the control of a structural and functional homologue of the genomic pyruvate decarboxylase 1 gene promoter, which replaces the genomic pyruvate decarboxylase 1 gene promoter, and wherein the pyruvate decarboxylase 1 on the host chromosome has been replaced with a single copy of the lactate dehydrogenase gene encoding the bovine-derived lactate dehydrogenase or its homologue. Porro et al. teach, "yeast

strains…transformed with at least one copy of a gene coding for lactic dehydrogenase (LDH) functionally linked to promoter sequences allowing the expression of said gene in yeasts" (page 4, lines 6-11). Porro et al. teach, "yeast strains having…a reduced pyruvate decarboxylase activity and transformed with…a gene coding for lactic dehydrogenase (LDH) functionally linked to promoter sequences" (page 4, lines 12-17). Porro et al. teach any yeast promoter…may be used according to the invention…the promoter of pyruvate decarboxylase gene of K. lactis (KlPDC) is particularly preferred (page 14, lines 18-28). Porro et al. further teach, "Pyruvate decarboxylase gene promoters…are particularly preferred" (page 15, lines 2-5). Porro et al. describe making a triple deletion of the pyruvate decarboxylase genes encoding PDC1, PDC5, and PDC6, using homologous recombination (page 8, lines 25-27). Porro et al. further teach that "PDC genes are highly conserved among different yeast genera" (page 9, lines 7-9). Porro et al. also teach "integrative vectors can be obtained by using homologous DNA sequences in certain regions of the host genome, allowing, by homologous recombination, integration of the vector" (page 12, lines 12-15).

Claim 17 is directed to the transformant according to claim 16, wherein the host is Saccharomyces cerevisiae. Porro et al. teach transformed yeast, Saccharomyces cerevisiae.

Claim 18 is directed to a lactic acid manufacturing method provided with a process for culturing the transformant described in claim 1, and a process for separating lactic acid from the cultured product obtained in said process for culturing the transformant. Porro et al. teach, "a process for the preparation of…lactic acid by

culturing the above described metabolically engineered yeast strains in a fermentation medium containing a carbon source and recovering lactic acid from the fermentation medium" (page 5, lines 5-10).

Porro et al does not explicitly teach a single embodiment of a transformed bacteria or yeast comprising a DNA for coding a foreign protein having lactate dehydrogenase activity operably linked to a functional homologue of the genome promoter of the pyruvate decarboxylase gene and in which the DNA has been homologously recombined to eliminate the host genome's pyruvate decarboxylase gene. However, Porro et al. teaches all of the structural elements (transformed yeast and bacteria; introduction of a foreign (bovine) lactate dehydrogenase gene; using a pyruvate decarboxylase promoter for expression of exogenous protein expression; and homologous recombination; knocking out the host genome's pyruvate decarboxylase gene). However, Porro et al. does not teach knocking out the host genome's pyruvate decarboxylase gene, by introducing a gene expression cassette in its place.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to make a single embodiment of a transformed bacteria or yeast comprising a DNA for coding a foreign protein having lactate dehydrogenase activity operably linked to a functional homologue of the genome promoter of the pyruvate decarboxylase gene and in which the DNA has been homologously recombined to eliminate the host genome's pyruvate decarboxylase gene.

Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior

art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Each of the elements (transformed yeast and bacteria; introduction of a foreign (bovine) lactate dehydrogenase gene; using a pyruvate decarboxylase promoter for expression of exogenous protein expression; homologous recombination; knocking out the host genome's pyruvate decarboxylase gene) are taught by Porro et al. and further they are shown to be used for the production of lactic acid. It would be therefore predictably obvious to use a combination of these elements in a recombinant bacteria or yeast.

In addition, Porro et al. also teach "integrative vectors can be obtained by using homologous DNA sequences in certain regions of the host genome, allowing, by homologous recombination, integration of the vector" (page 12, lines 12-15). A skilled artisan would be guided by the suggestion of Porro to generate a transgenic bacteria or yeast having lactate dehydrogenase integrated into the genome because in his teachings, Porro suggests using vectors capable of homologous recombination to introduce the foreign (bovine) lactate dehydrogenase into the microorganism.

Regarding eliminating the host genome's pyruvate decarboxylase gene by replacing it with a DNA cassette which includes "a DNA for coding a foreign protein having lactate dehydrogenase activity operably linked to a functional homologue of the genome promoter of the pyruvate decarboxylase gene," it would have been obvious because of a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the

product not of innovation but of ordinary skill and commonsense. The prior art teaches the need in the art to solve the problem of optimally producing a recombinant microorganism which has been knocked out for a pyruvate decarboxylase gene and further identifies a number of predictable potential solutions for making these deletions/ knockouts (by deletion of the gene; deletion or insertion of selectable markers, point-mutations, frame-shift mutations (Porro, page 10, lines 9-24)). One of ordinary skill in the art could have pursued the known potential option (of inserting the DNA cassette comprising pyruvate decarboxylase promoter/exogenous lactate dehydrogenase gene) with a reasonable expectation of success. It would be therefore predictably obvious to use a alternative method when eliminating the host genome's pyruvate decarboxylase gene.

Furthermore, codon optimization of the bovine lactate dehydrogenase gene for expression in Saccharomyces cerevisiae is well known in the art and therefore obvious.

Therefore the recombinant bacteria or yeast as taught by Porro et al would have been *prima facie* obvious over the recombinant bacteria or yeast of the instant application.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-3, 6-7 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claims 1 and 16 recite, “lactate dehydrogenase gene." According to standard meaning in the art a gene includes both the coding sequence and its promoter. In order clarify that the applicant does not want to implicitly include the LDH promoter in instant claims, some amendment is required to indicate that “lactate dehydrogenase gene" is “lactate dehydrogenase gene coding sequence." The applicant is invited to use any language which captures this meaning.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection.

Claim 1-7 and 16-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-28 of copending Application No. 12/324804 (US2009/0275095).

Instant claims 4-5 recite polynucleotide sequences (SEQ ID NOs:3-4) encoding bovine lactate dehydrogenase which has been codon optimized for expression in Saccharomyces cerevisiae. Claims 16-17 recite the same sequences. The claims of copending Application No. 12/324804 encompass the instant claims because they are

both directed to transgenic yeast comprising bovine LDH operatively linked to pyruvate decarboxylase promoter. Further they both claim methods of making lactic acid using these recombinant yeasts.

Allowable Subject Matter

Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SCOTT LONG/
Primary Examiner, Art Unit 1633